

Serial Number: 09/866,925
Attorney Docket: FELD3002/ESS

Remarks

Claims 20 and 21 are in the case. Claims 1-19 were previously canceled. Claims 22-35 are now canceled to simplify the issues. Claim 20 is amended as suggested in the Office Action.

We turn now to the rejections.

In paragraph 2, the claims are rejected under 35 U.S.C. § 101 for being non-statutory subject matter. The rejection takes the position that the claims are defective for not containing a useful result. Reconsideration is requested. The step in each of claims 20 and 21 is computer mediated detection and the useful result of said step in claim 20 and claim 21 is identifying certain sequences. Both claims involve acts of discovery. The undersigned refers to these acts as computational/computer mediated “microscopy”. No one would contend that the act of using a microscope for discovery purposes doesn’t constitute an enabled use or that modification of what is discovered does not constitute further discovery. It is submitted that in the same way the discovery of claims 20 and 21 is an enabled use per se. Reconsideration is requested.

In paragraph 4, claim 26 is rejected under 35 U.S.C. § 102(a) as being anticipated by Fleischman et al., Science 269, 496-512. Claim 26 has been canceled but it is submitted that Fleischman is irrelevant to claim 26 because claim 26 requires computer mediated detecting and Fleischman does not disclose this. Reconsideration is requested.

In paragraph 7, the claims are rejected under 35 U.S.C. § 112, first paragraph,

Serial Number: 09/866,925
Attorney Docket: FELD3002/ESS

as not being enabled because use of connectron sequences to predict gene expression is not enabled, because no evidence is furnished that connectron triplex structures will form or that if connectron triplex structures do exist that they control gene expression. At page 6 of the Office Action, it is stated that the specification provides guidance to identify connectron symmetries in genomic sequences.

Reconsideration is requested.

Firstly, the position in the Office Action is defective because as indicated in response to the rejection with 35 U.S.C. § 101, all that is necessary for enablement is what the Office Action admits is enabled, i.e. identification of connectron symmetries in genomic sequences.

Secondly, even if relying on identification/discovery alone is deemed by the PTO as insufficient, the PTO position is defective because the law is that applicant does not have to prove that triplex structures form within cells and have an effect on gene expression. Rather the burden of proof is on the PTO to prove that discovered four-sequence relationships will not result in triplex formation and effect on genome behavior. Casting doubt is not even enough. See Ex parte Reese, 40 U.S.P.Q.2d 1221 (Pat. Off. Bd. App. Int. 1996); In re Dinh-Hguyen, 181 U.S.P.Q. 46,47 (C.C.P.A. 1974) and In re Gardiner, 177 U.S.P.Q. 396, 397 (C.C.P.A.). The PTO has not met this burden.

Moreover, pro forma application of the Wands factors as carried out here does not cause the burden in the PTO to change to Applicant. No case says that such does.

The Wands factors are directed to showing lack of enablement in the facts of

Serial Number: 09/866,925
Attorney Docket: FELD3002/ESS

Wands as described in In re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). Consider also Ex Parte Forman, 230 U.S.P.Q. 546,547 (Bd. App. and int. 1986) relied on by Wands for the Wands factor.

The specific issue in Wands involved whether monoclonal antibodies necessary to practice the immunoassay method claimed were enabled without undue experimentation when practice involved unpredictable result screening negative hybridomas to find those that produced the desired antibodies.

In Foreman a question was whether mutant strains of *S. typhis* necessary for an oral vaccine were enabled when there was a lack of guidance leading to predictable results for obtaining mutant *S. typhis*.

The instant case differs from Wands and Foreman because no issue has been raised about treating agents or treating regimen. Thus the specific issues present in Wands and Foreman are not present here.

The issue according to Wand and Foreman is whether the application here describes how to computer mediate identification of connectrons and modification thereof. There is no contention that it does not.

Thirdly, it is noted that the applicant has applied the algorithm of this application to more than three hundred prokaryotic and Archae genomes and at least a dozen eukaryotic genomes. In every genome that has been examined, connectrons have been found. It is submitted that logic indicates that these have useful purpose. It is submitted that this is basis for a presumption that the connectrons are useful and that the claims are enabled. The PTO has not rebutted this presumption. It is submitted

Serial Number: 09/866,925
Attorney Docket: FELD3002/ESS

that this is independent basis for allowance.

We turn now to the indefiniteness rejection of paragraph 13 where the claims are rejected under 35 U.S.C. 112, second paragraph.

The rejection comprises the following:

Claim 20 is rejected as being indefinite for not indicating whether single stranded or double stranded DNA sequences are required. Claim 20 is amended to require double stranded DNA.

Claim 20 is rejected on the basis that it is not clear that C1 and C2 are adjacent sequences and are genomic sequences that are transcribed. It is noted that claim 20 does not refer to C1 and C2, that claim 20 is amended to recite adjacent RNA sequences and that claims 20 and 21 are directed to DNA sequences that control expression.

Fourthly, claim 21 is rejected as indefinite for requiring physical manipulation. In reply, it is submitted that the words in claims 21 "by computer" indicate computer mediated steps are instead required.

Fifthly, claim 26 is rejected as being indefinite in the phrase "sites of target application." Claim 26 is canceled.

Reconsideration of the rejections under 35 U.S.C. 112, second paragraph is requested.

It is submitted that applicant has made an effort to eliminate elements of controversy and to limit the claims being prosecuted to where only the legal issue of lack of enablement is present and has limited the claims being prosecuted to two in

Serial Number: 09/866,925
Attorney Docket: FELD3002/ESS

number. So far as the enablement issue is concerned applicant relies on a three pronged approach, (1) that the issue is misstated and that enablement is provided by what the Office Action admits is enabled, (2) that the rejection is legally defective because it switches the burden of proof for evidencing enablement to Applicant whereas the law is that the PTO is the party having the burden to provide evidence or reasoning proving that triplex structures do not form and cause gene control and (3) that what is claimed is a principle of nature with no deviations found and logic indicates that there is per se utility because of this. It is submitted that the discovery here is momentous and should be accorded patent protection in view of the above.

Allowance is requested.

Respectfully submitted,
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